REMARKS

I. Introduction

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

In the specification, paragraphs have been amended on pages 40 and 41.

Claims 12-15, 22-25, 27-28, 30-31, 33-34, 36-37, 44-47, 54-57, 64-67, and 70-92 are requested to be cancelled. The cancellation of claims does not constitute acquiescence in the propriety of any rejection set forth by the Examiner. Applicants reserve the right to pursue the subject matter of the canceled claims in subsequent divisional applications.

Claims 1-11, 16-21, 26, 29, 32, 35, 38-43, 48-53, 58-63, 68-69 are currently amended. Claim 93-95 are new.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Upon entry of this Amendment, claims 1-11, 16-21, 26, 29, 32, 35, 38-43, 48-53, 58-63, 68-69, and 93-95 will remain pending in the application.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Response to Issues Raised by Examiner in Outstanding Office Action

a. Application Status/Claim Disposition

Applicant elected Group I, with traverse, during the Response to Restriction Requirement and maintained that a search of the peptides provided in claim 1 is not unduly burdensome. Each of these sequences are related inventions and although the Office has

argued under MPEP § 806 that restriction is proper, Applicant is entitled to Examination of these inventions together in one application. As provided in MPEP § 808.02,

> Where ... the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions.

Applicant has canceled claims to antibodies and the other methods set forth in the Restriction Requirement. See Office Action, p. 2, for concerns regarding these inventions. In addition, Applicant has canceled claims to mimetics and inhibitors which the Office believes has different characteristics than the peptides of claim 1. Office Action, dated 08/26/2005, p. 2.

The remaining subject matter of claim 1 is from the same classification, field of search, and there is no indication of separate future classification. The peptides have all been classified by the Office into the same classification during the restriction requirement. Id. In addition, the peptides may be searched through analysis of the same database. There has been no suggestion that the claimed peptides will be classified in separate classifications in the future. No patents have been cited showing a separate status in the art when the peptides are classified together. As the inventions do not have a) a separate classification, b) a separate status in the art when considered together, or c) a different field of search, the Office should not require division of the application based on the peptides of claim 1. See MPEP § 808.02. Applicants respectfully request reconsideration and withdrawal of the restriction requirement with regards to the peptides of claim 1.

b. Specification

The Office has objected to the use of certain terms in the specification because they are not properly labeled as trademarks. Office Action, p. 3. Applicants have amended pages 40 and 41 to reflect the use of the marks and respectfully request withdrawal of the objection.

c. Sequence Compliance

The Office has objected to the application due to a failure to comply with the sequence requirements of 37 CFR 1.821 through 1.825. Office Action, p. 4. Applicants note that a preliminary amendment, a paper sequence listing and diskette, and a statement to

support filing and submission of these items in accordance with 37 CFR 1.821-1.825 was filed on February 27, 2004. Applicants believe the items of record are sufficient to address the Office's concerns. Applicants respectfully request reconsideration and withdrawal of the objection.

d. Oath/Declaration

Applicants will submit a new declaration before allowance of this file.

e. Claim Objections

Claims 68 and 69 are objected to for the use of the term "a" and "homology." Applicants have amended the claims as suggested by the Office and request withdrawal of the objection.

f. Claim Rejections - 35 U.S.C. § 112, Second Paragraph

Claims 1-5 and 68-73 are rejected under 35 U.S.C. § 112, second paragraph, as failing to set forth the subject matter, which applicant regard as their invention. Office Action, p. 14. Applicants have amended claims 2-5 and 68 as requested by the Office. Claim 1 has been amended to a proper Markush listing. Applicants have removed the term "altering" and respectfully request reconsideration and withdrawal of the rejection.

g. Claim Rejections - 35 U.S.C. § 112, First Paragraph

Claims 1-5 and 68-73 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Office Action, p. 6.

Applicant has canceled claims to dimers and trimers, as well as amended claim 1 to recite the isolated peptides provided. Applicant believes this addresses the Office's concerns regarding description of dimers, trimers, and fragments. Analysis of sequence identities is well understood by one of skill in the art. By aligning two sequences, the sequence identity can be readily calculated. Consequently, a person of skill in the art can readily envision the genus of sequences having at least 80% homology to the provided peptides.

Recent case law and PTO guidelines clarify the use of structural and functional relationships together to adequately describe an invention. For example, in *Enzo Biochem, Inc. v. Gene-Probe Incorporated (Enzo II)*, the court clarified that a genus claim to a species of nucleic acids based on their hybridization properties may be sufficient to describe a genus because such conditions indicate that all species within the genus will be structurally similar. See *Enzo II*, 323 F.3d 956, 967 (Fed.Cir. 2002), citing Synopsis of Application of Written Description Guidelines, Example 17. The current invention is to a group of peptides described in terms of their sequence identity to a known peptide and which are effective in decreasing the rate of degradation of type II collagen or the rate of chondrocyte hypertrophy. A peptide having the necessary structural and functional characteristics outlined in the application would have sufficient structural similarity to one of skill art and as provided in the PTO Guidelines to fulfill the written description requirement. Such a peptide would have sufficient similarity to affect the rate of collagen degradation and not just bind in a hybridization protocol, as provided in the PTO guidelines.

Claims 1-5 and 68-73 are rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. Office Action, pp. 8-14. The Office asserts, "the specification, while being enabling for the proteins [sic] set forth in SEQ ID NO: 3, does not reasonably provide enablement for any peptide fragment thereof or peptides or [sic] having at least 80% sequence homology to SEQ ID No: 3." As noted above Applicant amended claim 1 to the isolated peptides provided.

Applicants believe "[a]ny analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention." MPEP, 8th ed. Rev.2, 2164.01. See also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) (The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331,

1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied* , 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.* , 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). A person of skill in the art would be able to practice the claimed invention using methods described within the specification.

The rejected claims describe peptides that affect the rate of degradation of type II collagen or the rate of chondrocyte hypertrophy. Applicant has amended claim 1 to isolated peptides. The Office has conceded that the description in enabling for SEQ ID No: 3. Office Action, p. 8. Based on the specification and Examples, a person of skill in the art can make the peptides provided in claim 1 either through direct synthesis or recombinant technology. It is well known to one skilled in the art how to isolate peptides of the length described in claim 1. After isolating a peptide, a person of skill in the art may use the methods provided in the Examples to determine if the peptide has the required characteristics. As noted above, this type of peptide isolation and characterization through well defined methods are not undue experimentation. While this may be complex, the protocols are well understood by one of skill in the art and the experimentation is not undue. By following these protocols a person of skill in the art could design a peptide with 80% or 90% identity to the claimed peptides, or make 1-5 conserved amino acid substitutions, isolate and purify the peptide, and test it for the desired characteristic.

Taken together, the specification provides sufficient guidance for following the claimed methods to determine if a peptide affects the rate of degradation of type II collagen or the rate of chondrocyte hypertrophy. As noted above, as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Applicant respectfully requests reconsideration and withdrawal of the rejection.

h. Claim Rejections - 35 U.S.C. § 102

Claims 1 and 69 are rejected under 35 U.S.C. § 102(b) as being anticipated by Qvist (US 6,110,689). Claims 1 and 68-69 are rejected under 35 U.S.C. § 102(b) as being anticipated by Shriners (WO 94/14070). Office Action, p. 15. Applicants have amended claim 1 to clarify that the current claims encompass an isolated or purified peptide with the claimed sequences. Qvist and Shriners provide sequences of over 1400 amino acids in length. The isolated peptides of claim 1 are not described in Qvist or Shriners. A rejection under § 102 must anticipate every element of rejected claim. MPEP § 2131. As Qvist and Shriners do not describe the isolated peptides of claim 1 they cannot serve as the basis for a § 102 rejection. Applicants respectfully request reconsideration and withdrawal of the rejection.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant(s) hereby petition(s) for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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